National Patient Safety Alert

Department of Health & Social Care

NHS England

Shortage of Kay-Cee-L® (potassium chloride 375mg/5ml) (potassium chloride 5mmol/5ml) syrup

Date of issue:	26-Jul-24	Reference no:	NatPSA/2024/008/DHSC

This alert is for action by: All organisations involved in prescribing, dispensing and administering Kay-Cee-L® (potassium chloride 375mg/5ml) (potassium chloride 5mmol/5ml) syrup.

This is a safety critical and complex National Patient Safety Alert. Implementation should be co-ordinated by an executive lead (or equivalent role in organisations without executive boards) and supported by clinical leaders in paediatrics, GP practices and pharmacy services in all sectors.

Explanation of identified safety issue:

Kay-Cee-L® (potassium chloride 5mmol/5ml) syrup will be out of stock from late September 2024. The resupply date is to be confirmed.

The supply disruption is caused by an amendment to the manufacturing process, requiring re-formulation, and revalidation of the product.

Sando-K® (potassium bicarbonate 400mg and potassium chloride 600mg) effervescent tablets remain available and can support a full increase in demand. One effervescent tablet contains 12mmol potassium.

Unlicensed potassium chloride oral solutions manufactured within the UK are available via Specials manufacturers. NOTE A

Remaining supplies of Kay-Cee-L® syrup should be prioritised for patients requiring doses of less than 12mmol of potassium and where other preparations are not suitable (see Notes).

Care is needed to ensure selection of the most appropriate oral potassium supplement and delivery of the correct dosage.

Actions required

Actions to be completed 12/08/2024

Primary and Secondary care providers MUST:

1. Not initiate new patients on Kay-Cee-L® syrup.
2. Review all patients currently prescribed Kay-Cee-L® syrup to establish if potassium supplementation is still required, and switch to an alternative treatment, if considered necessary, ensuring no intolerance of excipients. NOTE B
3. Patients requiring doses of less than 12mmol of potassium should be prescribed:
   a. UK manufactured Special of potassium chloride oral solution NOTE A; or
   b. remaining supplies of Kay-Cee-L® syrup if Specials are not suitable.
4. Patients requiring doses of 12mmol potassium or more should be prescribed:
   a. Sando-K® effervescent tablets, where the dose can be rounded to the nearest whole tablet NOTE C or
   b. UK manufactured Specials of potassium chloride oral solution, if Sando-K® is not suitable. NOTE A
5. Clinicians should ensure any switch is clearly documented. Secondary care teams should inform primary care colleagues of any switches to a new product and any amendments to the patient's prescribed regimen.

For further detail, resources and supporting materials see: Enter specific webpage provided by alert issuer

For any enquiries about this alert contact: DHSCmedicinesupplyteam@dhsc.gov.uk

Failure to take the actions required under this National Patient Safety Alert may lead to CQC taking regulatory action

Additional information:

NOTES

A: Guidance on ordering and prescribing unlicensed medicines

The following Specials manufacturers have confirmed they can manufacture potassium chloride oral solution in various strengths:

- Nova Laboratories
- Target Healthcare
- Rokshaw Laboratories

Prescribers should work with local pharmacy teams to ensure orders are placed within appropriate time frames as lead times may vary. There may be other companies that can also manufacture this product. Specials are unlicensed medicines manufactured in the UK. The composition and strength of these presentations vary compared with the UK licensed product, so clinicians should refer to the Product Quality statement.

Any decision to prescribe an unlicensed medicine must consider the relevant guidance and NHS Trust or local governance procedures. Unlicensed medicines do not undergo any central quality assessment or suitability evaluation. Therefore, any import must be locally assessed in line with local unlicensed medicines processes.

B: Kay-Cee-L® syrup

- 1mL of syrup contains 1mmol of potassium and 1mmol of chloride
- Licensed for the treatment of hypokalaemia and potassium deficiency of renal and extra-renal origin.

Further information on excipient content and selection is available via the NPPG and RCPCH guidance: Choosing an Oral Liquid Medicine for children.

C: Sando-K® effervescent tablets

- ONE tablet contains 12mmol of potassium and 8mmol of chloride
- ONE tablet contains 0.1mmol of sodium and 521.5 mg of sucrose
- Licensed for the prevention and treatment of hypokalaemia

Doses of 12mmol potassium or more should be rounded to the nearest whole tablet.

Part-dosing of Sando-K® is not recommended. Further information on risks of part-dosing using effervescent tablets in children is available via the Specialist Pharmacy Service (Managing the risks of using effervescent tablets in Children) and the Neonatal and Paediatrics Pharmacists Group (NPPG) guidance (The Use of Calcium, Phosphate and Potassium supplementation in neonates and children).

References:

1. SmPC Kay-Cee-L® Syrup
2. SmPC Sando-K® effervescent tablets
3. BNF Potassium Chloride
4. BNFC Potassium Chloride
5. BNF Potassium Chloride with potassium bicarbonate
6. Medicines for Children: Potassium chloride for potassium depletion
7. Specialist Pharmacy Service: Managing the risks of using effervescent tablets in children
8. NPPG Guidance: Choosing an Oral Liquid Medicine for Children
9. NPPG Guidance: The Use of Calcium, Phosphate and Potassium supplementation in neonates and children.

Stakeholder engagement

The following stakeholders have been engaged in the management and consulted in the drafting of this alert: Specialist Pharmacy Service; Medicine Shortage Response Group; NHS England; national clinical experts in Paediatrics and Renal Services, national patient safety team; Medicines and Healthcare products Regulatory Agency and the Devolved Governments

Advice for Central Alerting System (CAS) officers and risk managers

This is a safety critical and complex National Patient Safety Alert. In response to CHT/2019/001 your organisation should have developed new processes to ensure appropriate oversight and co-ordination of all National Patient Safety Alerts. CAS officers should send this Alert to the executive lead nominated in their new process to coordinate implementation of safety critical and complex National Patient Safety Alerts, copying in the leads identified on page 1.